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Heart Failure and Cardiomyopathies

INITIAL SIX MONTHS RESULTS OF A NOVEL INTERATRIAL SHUNT THERAPY FOR HEART FAILURE WITH PRESERVED EJECTION FRACTION

Poster Contributions
Hall C
Monday, March 31, 2014, 9:45 a.m.-10:30 a.m.

Session Title: Heart Failure and Cardiomyopathies: Therapy V
Abstract Category: 14. Heart Failure and Cardiomyopathies: Therapy
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Background: To date, pharmacologic approaches have not proven effective in improving the pathophysiology or outcomes of patients with symptomatic heart failure in the setting of preserved or mildly reduced ejection fraction (HFpEF).

Methods: We investigated the safety and clinical efficacy of creating a small permanent inter-atrial shunt (IAS) to reduce LA pressure, using a novel IAS device (IASDTM) placed via conventional trans-septal approach in patients with symptomatic HFpEF, despite appropriate medical management.

Eleven patients were enrolled in a prospective multicenter feasibility study. Inclusion criteria were: LVEF > 45%; PCWP ≥ 15 mmHg (at rest), or ≥ 25mm Hg (during exercise); and ≥ 1 hospitalization for heart failure within prior 12 months or persistent NYHA Class III/IV for at least 3 months.

Results: Mean age and LVEF were 70±12 yrs and 57±9 %. The device was successfully implanted in each patient using echocardiographic guidance (TEE or ICE). At follow-up (Table), PCWP was reduced, with symptomatic improvement in 80% of patients, without development of new pulmonary hypertension. Two serious adverse events occurred (complete heart block requiring pacemaker and implant mal-position requiring new device) without ongoing issue after management.

Conclusion: This initial data demonstrates that placement of an interatrial shunt device in HFpEF patients is associated with favorable hemodynamic and clinical effects in the early to mid term. Further study of this approach is warranted.

Parameter	Baseline	Follow-up (days)	P value
mean PCWP (mmHg) (n=10)	19.4±2.8	14.0±3.2 (30-90)	0.003
m RAP (mmHg) (n=9)	10.8±2.9	11.8±3.0 (30-90)	ns
NYHA Class (n=5)	3	1.8±0.8 (180)	0.02
6 MWD (m) (n=4)	324±59	357±80 (180)	0.05
NT-Pro-BNP (pmol/L) (n=4)	245±225	205±186 (180)	0.07
MLWHF score (n=5)	45±20	24±14 (180)	0.07